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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,352	09/30/2003	Lee Johnson	NC 84,495	8469

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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/673,352	Applicant(s) JOHNSON ET AL.	
	Examiner Nathan A. Bowers	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 8-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>093003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a device for electroporating cells, classified in class 435, subclass 285.2.
- II. Claims 8-20, drawn to a method for electroporating cells, classified in class 435, subclass 173.6.

Inventions of Group II and Group I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus could be used in electroporation processes that do not require plating cultured cells onto a microwire electrode material. Instead, cells could be allowed to passively settle upon the electrode material after moving them into the fluidic device. Furthermore, the apparatus as claimed does not require the step of washing out unused substances from the chamber after electroporation.

During a telephone conversation with Thomas Robbins on 23 October 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-7 recite the limitation "the unit cells." There is insufficient antecedent basis for this limitation in these claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 1) Claims 1 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Hoff (US 20050054969).

Hoff discloses a device for electroporating subsets of cultured cells. The device comprises a conducting microwire material (Figure 1:16) connected to electrodes (Figure 1:14 and Figure 1:15). The electrodes are in communication with a stimulator array (Figure 1:12) capable of applying spatially variant voltages for electroporation.

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The stimulator array includes a voltage and/or current source S. This is described in paragraphs [0018]-[0021], [0036]-[0038] and [0043]. Hoff specifically teaches that the electrode materials form anodes and cathodes that cause electroporation when a voltage is applied. Paragraph [0022] states that a fluid flow chamber is used to deliver samples to the stimulator array and microwire electrode materials.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2) Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoff (US 20050054969) in view of Nicolelis (US 20060206161) and/or Dzekunov (US 20040197883).

With respect to claims 1, 2 and 5, Hoff discloses the apparatus as previously described above. As stated, it is believed that Hoff discloses a stimulator array in communication with the conducting microwire electrode materials. However, if Hoff's base (12) and associated voltage and current source cannot be considered a stimulator array, then Hoff fails to anticipate the claim.

Nicolelis discloses a high-density multichannel microwire electrode array for measuring cell response to electrical signals. Paragraphs [0056]-[0077] state that microwire arrays are implanted upon a computer controlled printed circuit board capable of receiving information derived from each individual electrode.

Hoff and Nicolelis are analogous art because they are from the same field of endeavor regarding electrical manipulation devices for cells.

At the time of the invention, it would have been obvious to position the microwire electrodes disclosed by Hoff upon a printed circuit board chip controllable by a computer. Nicolelis teaches that this arrangement is beneficial because it allows one to construct a high-density electrode array capable of interacting with a substantial number

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of cells simultaneously. Hoff already teaches that it is known to apply a time varying voltage of independent electrode clusters to induce electroporation. It would have been obvious to utilize a circuit board to accomplish this task because circuit board materials are inexpensive, easily machined, and capable of facilitating high densities of implanted microwire electrodes.

With respect to claims 1, 4 and 5, Hoff discloses the apparatus as previously described above. As stated, it is believed that Hoff discloses a fluid flow chamber in communication with the stimulator array and microwire electrodes. However, it is admitted that Hoff's offers only a limited description of the proposed fluid flow chamber in paragraph [0022].

Dzekunov discloses an electroporation device that comprises a fluid flow chamber through which cell samples are allowed to move. The chamber comprises electrodes that apply voltages sufficient to porate the cells as they flow through the chamber. The chamber includes inflow and outflow ports, valves, tubing, and a pump. This is described in Figure 12 and paragraphs [0191]-[0193] and [0240]-[0242].

Hoff and Dzekunov are analogous art because they are from the same field of endeavor regarding electroporation apparatuses.

At the time of the invention, it would have been obvious to ensure that the electroporation system proposed by Hoff is provided with a substantial fluid flow chamber that comprises access ports, valves, and a pump. Dzekunov teaches that flow cells are beneficial because they can be used to automatically porate and treat a large

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number of cells in a short amount of time. The use of an automatic flow cell system is desirable because it can be easily and inexpensively operated when compared to other electroporation systems.

With respect to claims 6 and 7, Hoff and Nicolelis/Dzekunov disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejections above. In addition, Dzekunov teaches multiple electrode configurations that are depicted in Figures 11 and 13 and described in paragraphs [0240] and [0247]. Figure 11 shows electrodes positioned within the chamber. Figure 13 shows electrodes (10) forming the top and bottom of the chamber. These configurations are well known in the art, and, accordingly, it would have been obvious to incorporate them into the system set forth by Hoff.

3) Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoff (US 20050054969) in view of Nicolelis (US 20060206161) and/or Dzekunov (US 20040197883) as applied to claim 1, and further in view of Merritt (US 20040241965).

Hoff and Nicolelis/Dzekunov disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the microwire electrode material comprises microwire glass hybridized to the simulator array with indium bumps.

Merritt discloses a high aspect ratio microelectrode array useful in the delivery and detection of electrical signals at discrete, spatially resolved locations. Paragraph

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[0037] indicates that it is known in the art to utilize indium bumps to make electrical connections between two arrays of electrical contacts.

Hoff, Nicoletis, Dzekunov and Merritt are analogous art because they are from the same field of endeavor regarding electrical manipulation devices.

At the time of the invention, it would have been obvious to connect the microwire glass electrodes to the simulator array using the well known process of indium bump bonding. Merritt teaches in paragraph [0037] that wire electrodes easily can be pushed into indium in order to create an electrical connection between an array of electronic unit cells and an array of microelectrodes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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